

# Adulterated Drugs and Other Supply Chain Threats

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**Asia-Pacific  
Economic Cooperation**

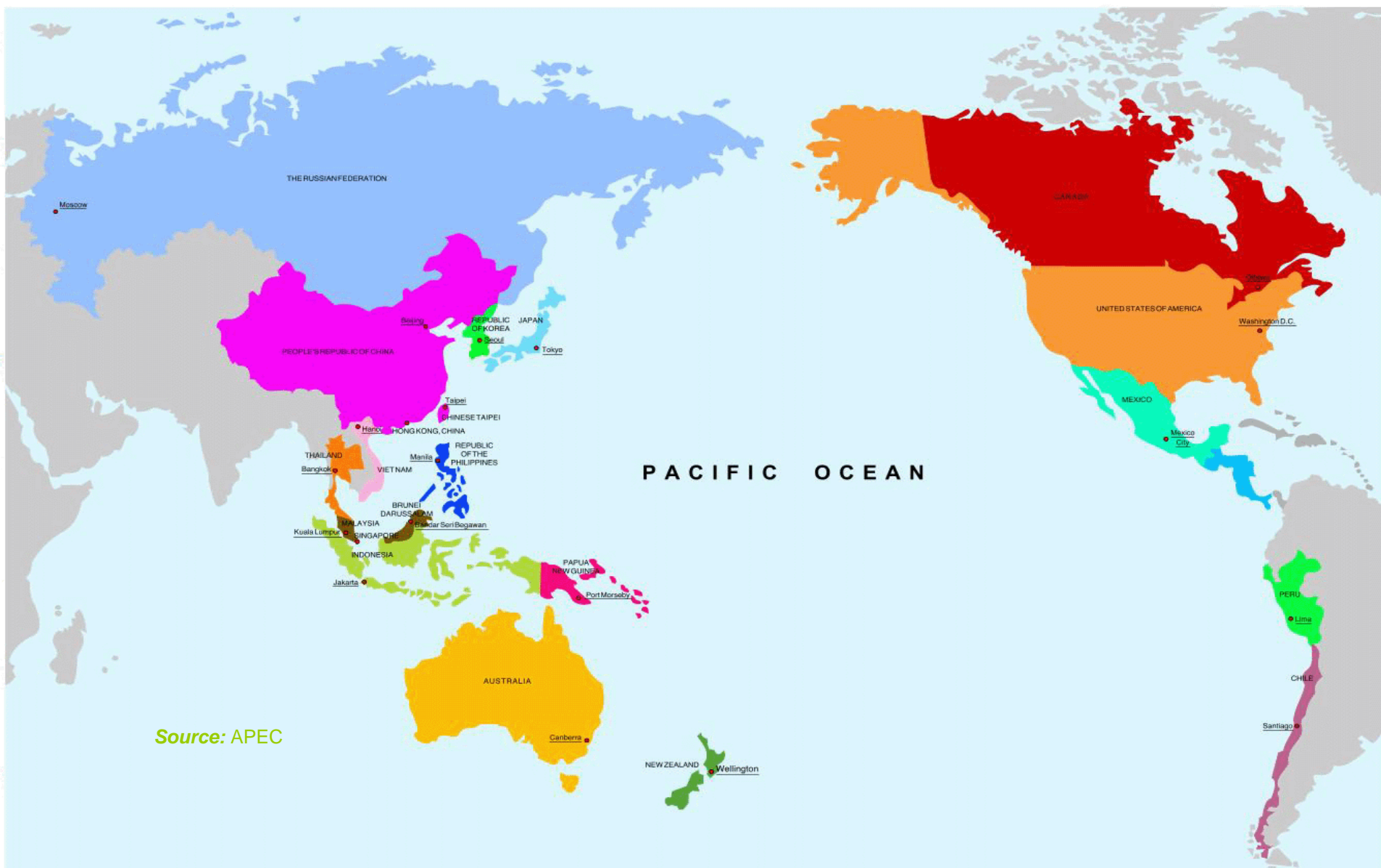
## Overview of APEC

- Asia-Pacific Economic Cooperation (APEC) created in 1989
- Currently comprised of 21 member economies
- Goals: Promote trade, sustainable economic growth and prosperity of member economies through policy alignment and economic and technical cooperation



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# APEC MEMBER ECONOMIES



Source: APEC

## APEC Operations

- APEC agenda and annual work plan developed around Senior Officials Meetings (top level bureaucrats across all Ministries/Departments), culminating in Leaders declaration
- APEC Chair rotates annually – host economy (Indonesia 2013, China, 2014, Philippines, 2015)
- APEC working level committees have an opportunity to promote workable policies
- Regulatory Harmonization Steering Committee reports through the Committee on Trade and Investment (CTI), one of four high working level committees
- Established procedures for funding project proposals



## RHSC Mandate and Goals

RHSC meant to formed to promote a more strategic, effective and sustainable approach to regulatory harmonization by:

- Proactively identifying and prioritizing projects seen to be of greatest value
- Promoting the establishment of APEC networks of technical experts and repository of reference materials
- Supporting mechanisms for the sharing of regulatory information and best practices



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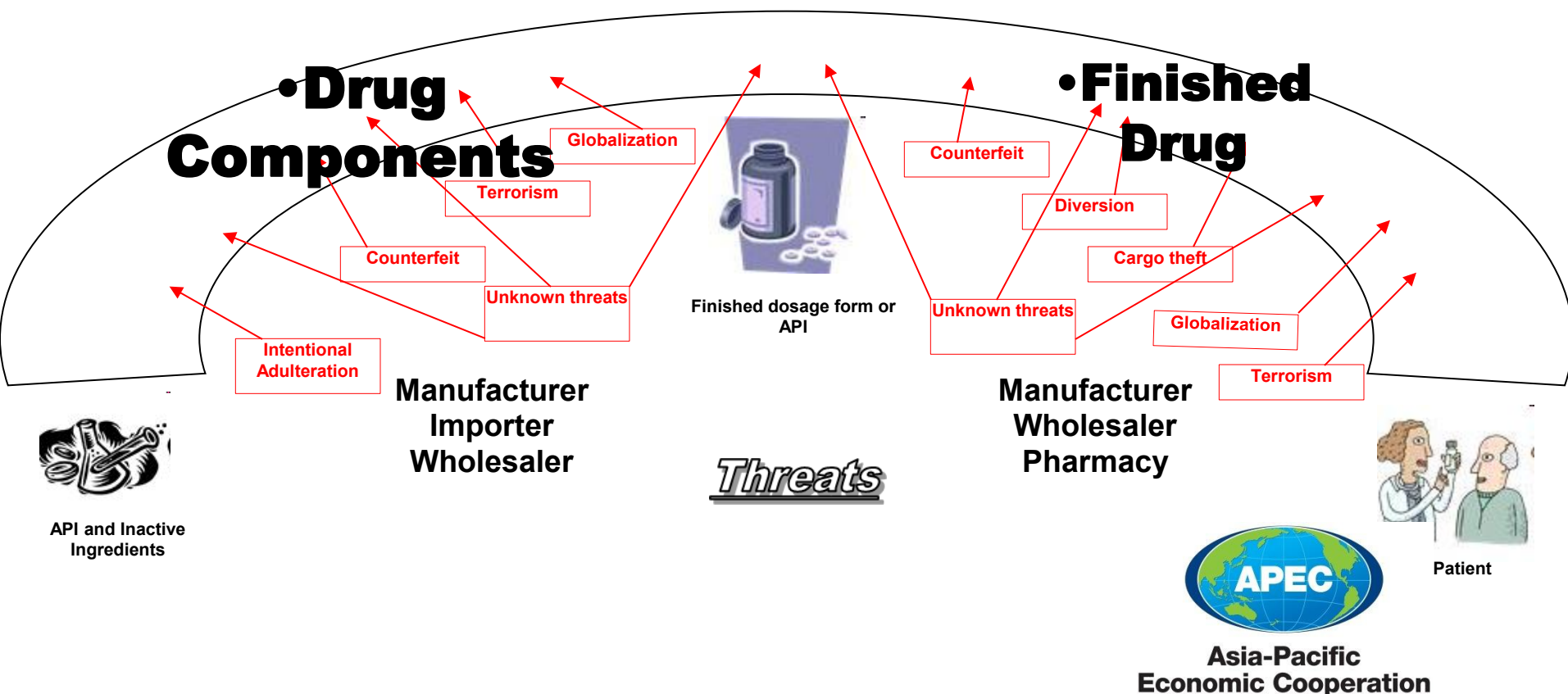
## Priority Work Areas

- Global Drug Integrity and Supply Chain (US)
- MRCTs – MHLW/PMDA
- Good Clinical Practice Inspection (Thai FDA)
- Good Review Practices (TFDA)
- Biosimilars
- Pharmacovigilance (AHC/KFDA)
- Combination Products



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# Threats Throughout the Drug Supply Chain





## APEC Roadmap for Global Medical Product Quality and Supply Chain Integrity

- Within APEC, work addressing counterfeits generally is ongoing, but for drugs, that work only addresses a subset of those that are adulterated and moving in international commerce.
- We need to ensure that our patients are receiving only those products that our individual member economies authorize to be on their market
- Globalization of drug industry creates significant challenges to regulatory authorities acting alone.
- Requires much better understanding of product development, raw material sourcing, requirements of manufacturing controls, and import and export operations



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## APEC Roadmap for Global Medical Product Quality and Supply Chain Integrity (2)

- To this end, FDA proposed and RHSC submitted to APEC a Multiyear Project Proposal.
- Only about a quarter of the funding would come from APEC, and the rest will come from participating RHSC members (typically, in-kind contributions).
- The draft proposal for RHSC covers:
  - Subcommittee formation led by RHSC
  - Conduct of a gap assessment between APEC members that will evaluate a number of important supply chain areas
  - Development of guidelines covering best practices, tool kits and other training materials
  - Development and initiation of a training program, including assessment tools
  - Assessments of the effectiveness of training programs and modification of format or content, as needed.



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# Project Tracking

KEY ISSUES	Gap Assess.	Tool Kits	Training	Effectiveness
cGMPs	X	X		
GDPs	X	X		
GI/EPs	X	X		
Product Identification, Authentication and Traceability	X	X		
Detection Technologies	X			
Internet Sales	X			
Single Point of Contact Systems	X	X		
Clinical and Retail Pharmacy Practices	X			
Surveillance and Monitoring	X	X		

# Case Study Factor VIII Ireland

## *Catastrophic Event*

*Failure of Supply Chain-*

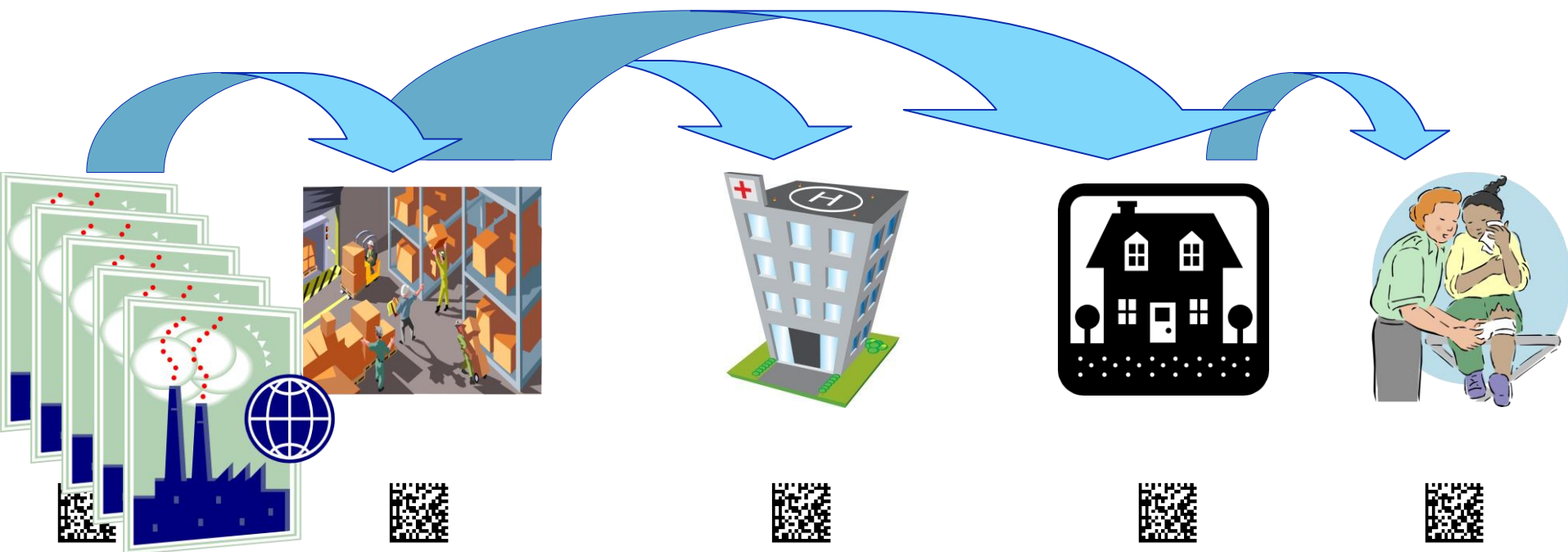
*Infection of patients with Hepatitis C and HIV due to contaminated blood products. **Infected medication remained in the supply chain after recall - leading to subsequent infection***

Over 70 people patients subsequently died as a direct consequence of adulterated Factor VIII

# Medication Supply chain.....where we are



# Where we need to be



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# Outcomes/ROI

## ***Validated Cold Chain delivery Service using Datamatrix Bar coding on medication packaging***

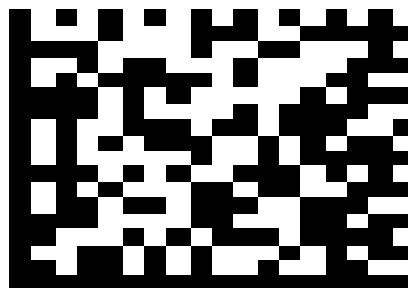
- Mock Recall identified location of all (100%) Medication within 10 minutes along with quantities of alternate stock available
- € 5 Million worth of medication stock removed from the supply chain

## Unintended Benefits

- 2000iu instead of recommended 1750iu
- Adherence > 90%
- Significant savings (over €70,000 within first 3 months with only 20 users)



# Why do we need global data standards for communication.....?







# Questions

